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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Yawei Ni, et al.

Serial No.: 10/059,627

Filed: January 29, 2002

For: **COMBINATION OF A GROWTH FACTOR AND A PROTEASE ENZYME**

Group No.: 1654

Examiner: Michael V. Meller

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

CERTIFICATE OF MAILING: I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on June 21, 2004.

Trish Paramore

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RESPONSE

Responsive to the Final Office Action dated May 4, 2004, and having a shortened statutory period for response expiring August 4, 2004, Applicants respectfully request reconsideration of this Application in view of the following remarks.

Pending in this application are Claims 1, 3, 5, 7, 13 – 15, 17, and 23 – 25.

I. Rejections Under 35 U.S.C. §103(a)

Claims 1, 3, 5, 7, 13 – 15, 17, and 23 – 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over European Patent No. 307847 (“EP 307847”), U.S. Patent No. 4,996,050

(“U.S. ‘050”), or International Patent Application No. WO 82/03772 (“WO 82/03772”), in view of European Patent No. 619370 (“EP 619370”), U.S. patent No. 5,589,451 (“U.S. ‘451”), U.S. Patent No. 5,814,605 (U.S. ‘605”), International Patent Application No. WO 97/13857 (“WO 97/13857”), or International Patent Application No. WO 98/16243 (“WO 98/16243”). The Examiner asserts that the references teach the use of plasminogen and KGF separately in pharmaceutical formulations and that it would have been *prima facie* obvious to combine the two ingredients. **Applicant respectfully asserts that no one of skill in the art would have combined (1) a protein-degrading enzyme and (2) a protein with a reasonable expectation of success.** The common wisdom is that the protein-degrading enzyme in such a combination will simply degrade the protein, hence rendering the protein ineffective.

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *See In re Merck & Co., Inc.*, 800 F.2d 1091 (Fed. Cir. 1986). Applicant recognizes that the prior art clearly teaches the use of the plasminogen protease enzyme alone and the KGF protein alone. However, **the prior art cannot be combined to reject the claimed combination of plasminogen and KGF because there is no reasonable expectation of success.** Plasminogen is a protease enzyme which degrades proteins. KGF is a protein. A combination of plasminogen and KGF would, according to expectation, result in the undesirable outcome of plasminogen acting to degrade KGF and destroy its activity. Without an expectation of success, the combination could not have been obvious.

Furthermore, **adding a protease enzyme to a prior art invention utilizing protein would render that prior art invention unsatisfactory for its intended purpose by destroying the protein.** If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *See In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

By way of example, it is common knowledge that, because of its basicity, a strongly basic solution is an effective disinfectant. It is also common knowledge that, because of its acidity, a strongly acidic solution is an effective disinfectant. However, it would not be obvious to

combine a strongly basic solution and a strongly acidic solution to produce an effective disinfectant because, according to common knowledge in the art, combining an acid and a base results in a neutral (neither basic nor acidic) solution having no disinfecting properties. Thus, contrary to the Examiner's assertion, it is not always obvious to combine individual components used separately for the same purpose in order to produce a new composition having similar activity. If the ingredients are known to react adversely to each other, like an acid and a base, or a protease enzyme and a protein, their combination is not obvious. If anything, the common wisdom is to **avoid** their combination.

Applicants respectfully assert that it would not have been obvious to combine plasminogen (which is a protease enzyme), with KGF (which is a growth factor protein). **Although pharmaceutical formulations have previously used protease enzymes and growth factor proteins independently, their simultaneous use is counter-intuitive. Protease enzymes degrade proteins.** See, Specification, Page 9, lines 7 – 18.

For these reasons, Claims 1, 3, 5, 7, 13 – 15, 17, and 23 – 25 are patentable over EP 307847, U.S. '050, or WO 82/03772, in view of EP 619370, U.S. '451, U.S. '605, WO 97/13857, or WO 98/16243.

II. Conclusion

Applicants respectfully submit that, in light of the foregoing comments, Claims 1, 3, 5, 7, 13 – 15, 17, and 23 – 25 are in condition for allowance. A Notice of Allowance is therefore requested.

Attorney Docket No.:
CARR-0084 (103216.00252)

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If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,

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Date